UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,006	11/15/2007	Campbell McInnes	CCI-067US	4495

959 7590 03/03/2010

LAHIVE & COCKFIELD, LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
LEE, JAE W	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
03/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,006	MCINNES ET AL.	
	Examiner	Art Unit	
	JAE W. LEE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29,33-35,37-43,45 and 47-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27, 29, 33-35, 37-43, 45 and 47-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

Claims 1-27, 29, 33-35, 37-43, 45 and 47-51 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13 and 41, drawn to a method of screening for a modulator of PLK, wherein the method comprises using the structure co-ordinates of Table 2, or a portion thereof.

Group II, claims 14-16, drawn to an assay for identifying a candidate compound capable of modulating PLK, said assay comprising the steps of: (a) contacting said candidate compound with PLK; and (b) detecting whether said candidate compound forms associations with one or more amino acid residues corresponding to PLK amino acid residues L59, G60, A65, C67, A80, K82, L130, E131, C133, R135, F183 and D194.

Group III, claims 17-19, drawn to a method of identifying a candidate compound capable of modulating PLK, comprising performing an assay using a compound selected from the following: (i) 5'-thioadenosine, or a derivative thereof; (ii) staurosporine, wortrnannin, purvalanol A, LY294002, quercetin, morin hydrate, or derivatives thereof; and (iii) 4-[4-(4-methyl-2-methylaminothiazol-5-yl)-pyrimidin-2-ylamino]-phenol; 4-[4-(2,4- dimethyl-thiazol-5-yl)-pyximidin-2-ylamino]-phenol or 4-[4-(2-amino-4-methyl-thiazol- 5-yl)-pyrimidin-2-ylamino]-phenol; or a pharmaceutically acceptable salt thereof.

Group IV, claims 20-25, drawn to a PLK modulator identified by the method of any one of claims 1 to 13, or a candidate compound identified by the assay according to any one of claims 14 to 19.

Group V, claims 26, 27, 29, 42, 43 and 45, drawn to a method of preventing and/or treating a PLK related disorder in a subject, comprising administering to said subject a PLK modulator or candidate compound according to any one of claims 20 to 24 and/or a pharmaceutical composition according to claim 25.

Group VI, claim 33, drawn to a computer for producing a three-dimensional representation of PLK wherein said computer comprises: (a) a computer-readable data storage medium comprising a data storage material encoded with computer-readable data, wherein said data comprises the structure co-ordinates of Table 2; (b) a working memory for storing instructions for processing said computer-readable data; (c) a central-processing unit coupled to said working memory and to said computer-readable data storage medium for processing said computer-machine readable data into said three- dimensional representation; and (d) a display coupled to said central-processing unit for displaying said three-dimensional representation.

Group VII, claim 34, drawn to a machine-readable data storage medium comprising a data storage material encoded with machine readable data, wherein the data is defined by at least a portion of the structure co-ordinates of Table 2.

Group VIII, claim 35, drawn to a method of predicting the structure and/or function of potential modulators of PLK, comprising using the computer of claim 33 or the machine readable data storage medium of claim 34.

Group IX, claims 37 and 38, drawn to a method of solving the crystalline form structure of a protein with significant amino acid sequence homology to a functional domain of PLK, comprising using at least a portion of the structure co-ordinates of Table 2.

Group X, claim 39 , drawn to a method of designing, selecting and synthesizing modulators of PLK, comprising using at least a portion of the structure co-ordinates of Table 2 in molecular design techniques.

Group XI, claim 40 , drawn to a method of developing compounds that can isomerise to reaction intermediates in the chemical reaction of a substrate and PLK-binding compound, comprising using at least a portion of the structure co-ordinates of Table 2.

Group XII, claims 47 and 48, drawn to a method of inhibiting PLK in a cell comprising contacting said cell with a compound selected from the following: (i) 5'-thioadenosine, or a derivative thereof; (ii) staurosporine, wortmannin, purvalanol A, LY294002, quercetin, morin hydrate, or derivatives thereof; and (iii) 4-[4-(4-methyl-2-methylaminothiazol-5-yl)-pyrimidin-2-ylamino]-phenol, 4-[4-(2,4- dimethyl-thiazol-5-yl)-pyrimidin-2-ylamino]-

phenol or 4-[4-(2-amino-4-methyl thiazol-5-yl)-pyrimidin-2-ylamino]-phenol; or a pharmaceutically acceptable salt thereof, such that PLK is inhibited in said cell.

Group XIII, claims 49 and 50, drawn to a fragment of PLK, or a homologue, mutant, or derivative thereof, comprising a ligand binding domain, said ligand binding domain being defined by the amino acid residue structural coordinates selected from one or more of the following: L59, G60, A65, C67, A80, K82, L130, E131, C133, R135, F183 and D194.

Group XIV, claim 51, drawn to a method of identifying a candidate compound capable of modulating PLK, comprising performing an assay using the fragment of PLK, or the homologue, mutant, or derivative thereof, according to claim 49.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Cheng et al. (The crystal structure of the human polo-like kinase-1 polo box domain and its phospho-peptide complex, The EMBO Journal Vol. 22 No. 21 pp. 5757-5768, published on 11/03/2003) teach a method of screening a modulator of the human polo-like kinase-1 (PLK-1), which is identical to Applicants' PLK (see Example 2 of the specification), wherein the method comprises using the structural coordinates determined for the crystal of the PLK-1 and a modulator, i.e., the phospho-peptide (see Figure 4 (B) and its legend), which meets the limitation of claim 1, in the recitation of "[a]

method of screening for a modulator of PLK, wherein the method comprises using the structure co-ordinates of Table 2, *or a portion thereof*", which encompasses the use of any single atomic coordinate of Table 2 (italicized for added emphasis), and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656